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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/528,682	03/20/2000	Mariagrazia Pizza	0342.105	5794

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EXAMINER

BORIN, MICHAEL L

ART UNIT	PAPER NUMBER
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1631

DATE MAILED: 05/29/2003

20

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/528,682

Applicant(s)

Pizza et al.

Examiner

Michael Borin

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Feb 25, 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 7-32 is/are pending in the application.
- 4a) Of the above, claim(s) 30-32 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 7-29 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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DETAILED ACTION

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 11/18/02 has been entered.

Status of the claims

2. Response to election of species filed 02/25/2003 are acknowledged. Polynucleotides that encode polypeptide numbered relative to SEQ ID No. 1 is elected with traverse. Applicant questions the distinctness of the species. SEQ ID Nos 1-4 are porcine and different human variants of LT-A polypeptide having different sequences. A fragment of 8 residues or more ¹ will be different for peptides having different sequence. The election of species requirement is still deemed proper and is therefore made FINAL. Claims 30-32 are withdrawn from consideration as drawn to

¹note that, as claimed, the fragment can be from any part of full-length polypeptide, as long as it contains Arg residue

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non-elected species but will be address if the claims drawn to elected species are deemed to be allowable. Rejections of claims 30-32 are not addressed in this Office action.

Applicant's arguments have been fully considered and were deemed persuasive-in-part. The following rejections constitute the complete set presently being applied to the instant application.

Drawings

3. The status of Fig. 12 is not clear. The proposed drawing Fig. 12 was filed on 05/21/02 (paper #12) but is absent from the set of formal drawings filed subsequently on 6/21/2002 (paper #14).

It is noted that the previous Office action objected the proposed drawing Fig. 12 because it introduced new matter into the drawings. The original disclosure does not support the showing of sequences as resented on Fig. 12.

Claim Rejections - 35 USC § 112, second paragraph.

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4. Claim 7, and claims 8-29 dependent thereupon, are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The rejection is applied for the following reasons:

Claim 7 as amended is ambiguous in relation to the structure of the product: In (i) the claim allows for the encoded polypeptide to be 8 residues long, whereas in (ii) it requires position 72 to be present. How can an octapeptide have a residue in position 72? How a short peptide be "numbered relative to SEQ ID No. 1"?

Further, claim 7 remains ambiguous in regard to amino acid residue at position 72. As clearly stated in the disclosure, this residue is Ala; hence part (ii) of claim 7 seem to require presence of Ala in the peptide. On the other hand, part (iii) of the claim states that this residue is Arg.

Claim Rejections - 35 USC § 102 and 103.

5. Claims 7-29 remain rejected under 35 U.S.C. 103(a) as being unpatentable over EP 145486. The rejection is maintained for the reasons of record.

Examiner strongly disagrees with applicant that the peptide addressed in the claims has a residue which has such distinguishing characteristics as (1) being numbered as #72, and (2) being a "mutated residue". All that parts (ii) and (iii) of

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claim 7 specify is that the peptide contains Ala residue some place. The situation would have been different if the claims addressed specific, rather than random, fragment of LT-A (e.g., polypeptides comprising fragment x-y of SEQ ID No. Z). As was stated in the previous response, aside from the fact that SEQ ID No. 1 is a new matter (see above), the only meaning that Examiner reads into the limitation that the fragment comprises "amino acids residue corresponding to Ala-72 of SEQ ID No. 1" is that the residue which is being replaced as claimed has to be a residue corresponding to Ala,, i.e., it has to be any Ala replaced by any, in this case, Arg residue. Any Ala residue will be "corresponding" to any other Ala residue because they are the same by their nature.

6. Claims 7-29 remain rejected under 35 U.S.C. 102(b) as anticipated by Burnette et al (US Patent 5,770,203). The rejection is maintained for the reasons of record and in view of the comments made in the preceding paragraph in regard to rejection over EP 145486.

Conclusion.

7. No claims are allowed.

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8. This is a RCE of applicant's earlier Application No. 09/528682. All claims are drawn to the same invention claimed in the earlier application and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the earlier application. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action in this case. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no, however, event will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael Borin whose telephone number is (703) 305-4506. Dr. Borin can normally be reached between the hours of 8:30 A.M. to

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5:00 P.M. EST Monday to Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mr. Michael Woodward, can be reached on (703) 308-4028. The fax telephone number for this group is (703) 305-3014.

Any inquiry of a general nature or relating the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

May 28, 2003

mlb

MICHAEL BORIN, PH.D
PRIMARY EXAMINER

